

EXPRESS MAIL NO. EK102656653US

FORM PTO 1390 (REV 10-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER P02232US0 (10105701)
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>09/889772</b>
INTERNATIONAL APPLICATION NO. PCT/SE00/00017	INTERNATIONAL FILING DATE 12 January 2000	PRIORITY DATE CLAIMED 26 January 1999	
TITLE OF INVENTION MATERIALS FOR PACKAGING NICOTINE-CONTAINING PRODUCTS			
APPLICANT(S) FOR DO/EO/US Gustav Levander, Anders H. Karlsson, and Ingemar Hildingsson			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371 (f)).</li> <li>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).</li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</li> <li>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> </ol>			
Items 11 to 16 below concern document(s) or information included:			
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 &amp; 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A <b>FIRST</b> preliminary amendment.  <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>14. <input type="checkbox"/> A substitute specification.</li> <li>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>16. <input checked="" type="checkbox"/> Other items or information:</li> </ol>			
Certified Copy of Priority Application Certificate of Registration			

EXPRESS MAIL NO. EK102656653US

U.S. APPLICATION NO. <b>09/889772</b> (known as 37 CFR 1.53)	INTERNATIONAL APPLICATION NO. PCT/SE00/00017	ATTORNEY'S DOCKET NUMBER HO-P02232US0
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17. ☒ The following fees are submitted:

**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

☒ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO .....\$1000.00

☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .....\$860.00

☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO .....\$710.00

☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) .....\$690.00

☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) .....\$100.00

**ENTER APPROPRIATE BASIC FEE AMOUNT =** \$ 1000.00

Surcharge of \$ 130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	32-20 =	12	x 18.00	\$	216.00
Independent claims	7-3 =	4	x 80.00	\$	320.00
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				x	\$
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	1,666.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$	
<b>SUBTOTAL =</b>				\$	1,666.00
Processing fee of \$ _____ for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +				\$	
<b>TOTAL NATIONAL FEE =</b>				\$	1,666.00
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). Assignment must be accompanied by appropriate cover sheet (37 CFR 3.28, 3.31) ( _____ per property).				+	\$
<b>TOTAL FEES ENCLOSED =</b>				\$	1,666.00

	<b>Amount to be Refunded:</b>	\$
	<b>Charged:</b>	\$

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

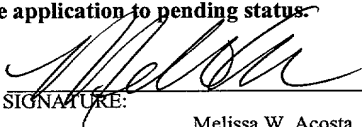
b. ☒ Please charge my Deposit Account No. 06-2375 in the amount of \$ 1,666.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to my Deposit Account No. 06-2375. A duplicate copy of this sheet is enclosed.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

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 (713) 651-5407

  
 SIGNATURE: \_\_\_\_\_  
 NAME: \_\_\_\_\_  
 45,872  
 REGISTRATION NUMBER \_\_\_\_\_  
 DATE: JULY 20, 2001

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EK102656653US, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date shown below.

Dated: July 20, 2001

Signature:   
(Melissa W. Acosta)

Docket No.: P02232US0  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Gustav Levander, Anders H. Karlsson, and Ingemar  
Hildingsson

Application No.: Not Yet Assigned

Group Art Unit: N/A

Filed: July 20, 2001

Examiner: Not Yet Assigned

For: MATERIALS FOR PACKAGING NICOTINE-  
CONTAINING PRODUCTS

**FIRST PRELIMINARY AMENDMENT**

Box Patent Application  
Commissioner for Patents  
Washington, DC 20231

Dear Sir:

Applicants respectfully request that the below amendments be made prior to examination of this application.

**In the Specification**

Please substitute the following new title for the title of the PCT application.  
Applicants have enclosed in Appendix A a marked version showing the changes contained herein.

"Materials for Packaging Nicotine-Containing Products"

Please amend the specification as follows:

On page 1, line 1 of the specification, please insert the following.

This application is a U.S. National Stage of International Application No. PCT/SE00/00017, which was filed on January 12, 2000 and claims priority to Swedish Application No. 9900215-6, which was filed on January 26, 1999.

### **In the Claims**

Please enter the below substitute claims for claims 1-8, and 10-12. Please cancel claims 9 and 13 without prejudice and without acquiescence.

1. (Amended) A material for packaging a nicotine-containing product comprising a polymer based on dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.
2. (Amended) A material for packaging a nicotine-containing product comprising a liquid crystal polymer (LCP).
3. (Amended) The material according to claim 1, wherein the polymer is polyethylene naphthalate (PEN).
4. (Amended) The material according to claim 1, wherein the polymer is polytrimethylene naphthalate (PTN).
5. (Amended) The material according to claim 2, wherein the LCP comprises hydroxy benzoic acid and hydroxy naphthenic acid.

6. (Amended) The material according to claim 1, further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).

7. (Amended) The material according to claim 1, wherein the material is laminated with one or more metals or polymer foils.

8. (Amended) The material according to claim 7, wherein the metal is aluminum foil.

10. (Amended) A method of packaging a nicotine containing product comprising the step of providing a polymer material for a mould or an equivalent to cast the nicotine containing product into its final shape upon solidification in the package, wherein the polymer material is based upon dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.

11. (Amended) The method according to claim 10, wherein the final form of the nicotine containing product is a tablet or a lozenge.

12. (Amended) The material according to claim 1, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.

Please enter the following new claims.

14. A material for packaging a nicotine-containing product, comprising a polymer based on a combination of dimethyl-2,6 naphthalene dicarboxynate and 2,6-naphthalene dicarboxylic acid monomers.

15. The material according to claim 2 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
16. The material according to claim 14 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
17. The material according to claim 14, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.
18. The material according to claim 14, wherein the material is laminated with one or more metals or polymers.
19. The material according to claim 18, wherein the metal is aluminum foil.
20. The material according to claim 2, wherein the material is laminated with one or more metals or polymers.
21. The material according to claim 20, wherein the metal is aluminum foil.
22. The material according to claim 2, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.

23. A method of packaging a nicotine containing product comprising the step of enclosing totally the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphtalene dicarboxylic acid monomers.
24. The method according to claim 23, wherein the polymer is polyethylene naphtalate (PEN), polytrimethylene naphtalate (PTN) or a liquid crystal polymer (LCP).
25. The method according to claim 23 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
26. The method according to claim 23, wherein the material is laminated with one or more metals or polymers.
27. The method according to claim 23, wherein the metal is aluminum foil.
28. The method according to claim 23, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.
29. A method of packaging a nicotine containing product comprising the step of enclosing partially the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphtalene dicarboxylic acid monomers.

30. The method according to claim 29, wherein the polymer is polyethylene naphthalate (PEN), polytrimethylene naphthalate (PTN) or a liquid crystal polymer (LCP).
31. The method according to claim 29, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.
32. A method of packaging a nicotine containing product comprising the step of sealing the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.
33. The method according to claim 32, wherein the polymer is polyethylene naphthalate (PEN), polytrimethylene naphthalate (PTN) or a liquid crystal polymer (LCP).
34. The method according to claim 32, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.



## REMARKS/ARGUMENTS

Claims 1-13 were filed in the original application. Claims 9 and 13 have been canceled and claims 14-34 have been added to this application. The claims have been amended for the sake of clarity. Therefore, these amendments do not narrow the scope of the claims within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 586, 56 USPQ2d 1865, 1886 (Fed. Cir. 2000). No new matter has been added by these amendments. Thus, entry of these amendments prior to examination is respectfully requested.

Attached hereto, as Appendix A, is a marked-up version of the changes made to the specification and claims by the current amendment.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: July 20, 2001

Respectfully submitted,

By 

Melissa W. Acosta

Registration No.: 45,872

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## Appendix A

### Version With Markings to Show Changes Made

#### Title:

New Use Materials for Packaging Nicotine-Containing Products

#### In the claims:

1. (Amended) A material for packaging a nicotine-containing product, comprising ~~characterized in that it comprises~~ a polymer based on dimethyl-2,6 naphthalene dicarboxynate ~~and/or~~ 2,6-naphthalene dicarboxylic acid monomers.
2. (Amended) A material for packaging a nicotine-containing product, comprising ~~characterized in that the material comprises~~ a liquid crystal polymer, (LCP).
3. (Amended) ~~A~~ The material according to claim 1, wherein ~~characterized in that~~ the polymer is polyethylene naphthalate, (PEN).
4. (Amended) ~~A~~ The material according to claim 1, wherein ~~characterized in that~~ the polymer is polytrimethylene naphthalate, (PTN).
5. (Amended) ~~A~~ The material according to claim 2, wherein ~~characterized in that~~ the LCP comprises hydroxy benzoic acid and hydroxy naphthenic acid.
6. (Amended) ~~A~~ The material according to ~~any one of the preceding claims~~ 1, ~~characterized in that it further comprises~~ comprising other polymer(s), ~~preferably one of more~~ selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA),

polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).

7. (Amended) A The material according to anyone of the preceding claims 1, wherein the material characterized in that it is laminated with one or more metals and/or polymers foil(s).

8. (Amended) The A material according to claim 7, characterized wherein the metal in that it is laminated with aluminum foil.

10. (Amended) A method of packaging a nicotine containing product comprising the step of A material according to anyone of the preceding claims, characterized in that it is used for a package that is provided providing a polymer material for a with moulds or an equivalent into which to cast the nicotine containing product into its final shape is cast a substance that upon solidification in the package. receives its final form and shape, wherein the polymer material is based upon dimethyl-2,6 naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.

11. (Amended) The method according to claim 10, wherein the final form of the nicotine containing product is A material according to claim 10, characterized in that it is used for a package in which are directly cast a tablets or a lozenges.

12. (Amended) The A material according to anyone of the preceding claims 1, wherein the nicotine containing product is characterized in that it is used for packaging a patch for transdermally administering nicotine, a nicotine containing chewing gum, a nicotine

~~containing tablet, a spray for nasal administration of nicotine, or a device for inhaling~~  
nicotine an inhaler.

## NEW USE

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### Technical field

The present invention relates to materials for packaging nicotine-containing products.

### Background art

For many years tobacco smoking has been one of the major health problems throughout the world. Smoking is now recognized as the main cause for e.g. high blood pressure and lung cancer. However, because of the addictive nature of nicotine it is utterly difficult for heavy smokers to completely stop smoking. An acceptable alternative to smoking has been to provide nicotine in a form or manner other than by smoking, e.g. as a chewing gum containing nicotine as an active ingredient, see e.g. US 3,845,217. Other products used as substitutes for smoking are tablets containing nicotine, see e.g. US 5,543,424, devices for allowing nicotine to be inhaled through an elongated tube, see e.g. US 5,501,236, nicotine containing nasal sprays, see e.g. US 5,656,255, patches for administering nicotine transdermally, see e.g. US 4,915,950, etc.

The primary requirement when packaging drugs and food is the demand that the package must protect the product against penetration of moisture and oxygen from the environment. Very seldom the product itself constitutes any problems. Nicotine, on the other hand, is very aggressive towards its environment and migrates through most known materials. It is also very hygroscopic and therefore sensitive to moisture and when exposed to oxygen or air the nicotine turns brown. Because of the toxicity of nicotine and because the expected shelf-life for nicotine containing products is as long as up to two years, commonly used materials within the package industry, e.g. polypropylene, polyethylene and polyvinyl chloride therefore cannot be used for nicotine containing products.

A known polymer which fulfills the requirements of oxygen, water and nicotine impermeability is commercially available under the trademark Barex<sup>®</sup>, being a copolymer made of acrylonitrile and methylmethacrylate and grafted to nitrile rubber on the main chain. Due to the copolymerization with methylmethacrylate the polymer becomes softer and is possible to process. Barex<sup>®</sup> is available with different amounts of nitrile rubber, is amorphous and is a glass polymer at room temperature.

The temperature range within which Barex<sup>®</sup> may be processed is, however, very narrow rendering the polymer difficult to process resulting in a large amount of discarded material. This is partly due to Barex<sup>®</sup> having a temperature dependent elasticity. Today, Barex<sup>®</sup> is also associated with a high price.

5 The use of Barex<sup>®</sup> in a nicotine impermeable container is disclosed in US 5,501,236.

### Summary of the invention

It is therefore an object of the present invention to provide an alternative material to Barex<sup>®</sup>, which exhibits favorable characteristics of oxygen, water and nicotine impermeability, but which does not suffer from the above-mentioned drawbacks. According to  
10 the invention it is therefore suggested an alternative nicotine impermeable packaging material for a nicotine-containing product having the characterizing features of the claims.

The material of the invention comprises polyethylene naphthalate, polytrimethylene naphthalate and/or a liquid crystal polymer, LCP, and has excellent characteristics of oxygen, water and nicotine impermeability. Due to the temperature ranges the polymers of the invention are favorable to process and will have an acceptable price. The material of the invention is known *per se*, but its excellent nicotine barrier properties have not been known. Neither has its use for making packages for nicotine-containing products been  
15 20 contemplated.

### Detailed description of the invention

The packaging material of the invention is intended for use in connection with nicotine containing products for therapeutic treatment of patients having an addiction to nicotine. Examples of such products are chewing gums, sublingual tablets, nasal sprays,  
25 nicotine patches and nicotine inhaling devices, all marketed through Pharmacia & Upjohn. These products are all classified as drugs and thus, the requirements of product stability are high. The expected shelf life is two years without any noticeable change regarding composition, concentration and dosage. Specific ranges for allowed variations have been established in accordance with requirements from the authorities, e.g. Food  
30 and Drug Administration, FDA, in the USA.

In chewing gums the nicotine is usually present in the form of a complex with an insoluble cation-exchanger, which is disbursed in a gum base, in order to be stabilized. In

tablets the nicotine is usually present in the form of an inclusion complex. Only small amounts, if any, of nicotine are in contact with the package for chewing gums and tablets and thus, the demand for a nicotine barrier becomes lower for these products. The pH for a chewing gum is usually slightly above 4.

5 In nasal spray the nicotine is present in a liquid solution having a concentration of approximately 10 mg/ml and a pH of approximately 7. The nasal spray is distributed in glass flasks inert to the aggressiveness of nicotine. However, the nicotine solution also comes into contact with seals and pumping devices made of polymeric material.

10 In a patch and in an inhaling device primarily nicotine vapor comes into contact with the package. Here the concentration depends on the vapor pressure of the nicotine that varies with temperature. In room temperature the concentration in a patch is approximately 250 mg/ml. In a patch and in an inhaling device the pH is approximately 9 - 10.

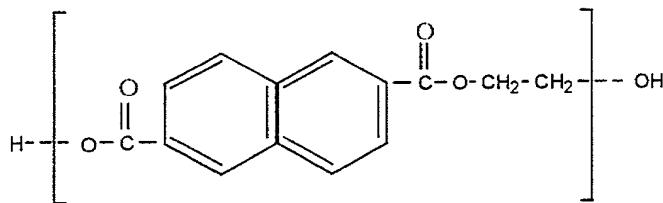
15 A number of factors are important when materials for nicotine-containing packages are chosen. The nicotine must not migrate through the packaging material and disappear from the system or be accumulated uncontrollably in the packaging material. Also, the nicotine must be protected from oxygen due to the fact that it is easily decomposed in contact with air or oxygen. Products containing nicotine also turns brown or yellow when only small amounts of decomposition products are present resulting in cosmetic drawbacks long before any stability limits have been passed. A good oxygen barrier is  
20 therefore of utmost importance.

Besides the above mentioned primary demands on good nicotine resistance and low oxygen permeability, other important factors to take into consideration regarding packaging materials for nicotine-containing products are water and moisture permeation,  
25 processability, price and environmental impact.

The water barrier is important especially in the nasal spray where loss of water has large impact on the concentration of the product. Water barrier characteristics are also important in other forms of distribution since water may have an impact on permeation characteristics of the polymer. Great consideration should also be taken to the process-  
30 ability since large-scale industrial production is considered where even small problems may involve large costs.

With the aim to find a packaging material for the packaging of a nicotine-containing product, which fulfills the above mentioned demands two different types of polymers, were found.

The first of these materials is PEN, polyethylene naphthalate:

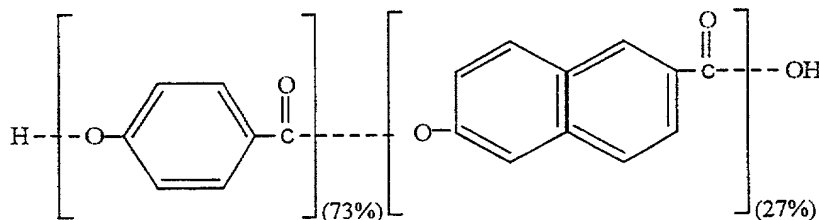


PEN is polyester based on dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers. Dimethyl-2,6-naphthalene dicarboxynate and -2,6-naphthalene dicarboxylic acid monomers are e.g. sold by Amoco under the trade name NDC and NDA-monomer respectively. PEN is semicrystalline and is a glass polymer at room temperature.

There are other polymers, such as PTN (polytrimethylene naphthalate) which are based on the same monomers. PTN differs from PEN only in that the ethylene chain has been exchanged to a propylene chain. It is also envisageable to use polymers comprising both dimethyl-2,6-naphthalene dicarboxynate or 2,6-naphthalene dicarboxylic acid monomers.

PEN differs from PET (polyethylene tereftalate), which is another, more commonly used polyester, in that the benzene ring in the PET molecule has been exchanged for naphthalene in PEN. This makes the PEN structure more rigid than the PET structure and the features of PEN more favorable for this invention than the features of PET.

The second nicotine impermeable polymer of the invention is polyester based Liquid Crystal Polymer, LCP. One example thereof is Vectra<sup>®</sup> A 530 having the following structure:





LCPs constitute a group of materials, which have a characteristic molecular structure. LCP polymers consist of rigid rod-like macromolecules that align in the melt to produce a liquid-like structure. This specific structure brings considerable improvement in mechanical properties compared with conventional polymers and a number of other exceptional properties. The monomers are hydroxy benzoic acid and hydroxy naphthenic acid. A typical LCP polymer, such as the above-mentioned Vectra® A 530, is filled with 30 % of mineral filler. The LCP material has a dense structure as a consequence of high crystallinity, is chemically resistant and has extremely low diffusion rates for oxygen and water.

According to the invention it was surprisingly found that in addition to the above mentioned barrier properties against water and oxygen PEN, PTN and LCP also exhibit excellent barrier properties against nicotine. In below Table 1 is shown a comparison of the properties of Barex® 210, PEN 14991 and Vectra® A 530. For comparison is added a polymer, Isoplast 2530 (a polyurethane having better barrier characteristics than other polyurethanes due to its high glass transition temperature), which does not have good nicotine impermeability.

Barex® is marketed by British Petroleum, PEN by Shell and by Eastman, Vectra® by Ticona and Isoplast by Dow.

**Table 1**

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Opacity	Transparent	Transparent	Opaque	Transparent
Morphology				
Crystallinity	Amorphous	Semi crystalline	High Crystalline	Amorphous
Permeability				
Oxygen cm <sup>3</sup> ·mm/m <sup>2</sup> ·day·atm	0,3	1,5	0,02	2,4
Water g·mm/m <sup>2</sup> ·day	2.0	0,7	0,05	1,2

Material Properties				
Material	Barex 210	PEN 14991	Vectra A 530	Isoplast 2530
Nicotine	Excellent	Excellent	Excellent	Not acceptable
Resistance		Equivalent to Barex	Equivalent to Barex	Inferior to Barex
Processing				
Extrusion	+	+	+	+
Injection Molding	+	+	+	+
Vacuum	+	+	-	
Forming				
Blow Molding	+	+		+
Applications				
Film	+	+	+	+
Laminate	+	+	+	+
Injection Mould details	+	+	+	+
Blow Mould details	+	+		+
Blisters	+	+	-	

The nicotine resistance of the captioned polymer materials was investigated with sorption tests as follows. Pieces of the respective materials were placed in glass bottles containing nicotine solution and were stored therein at room temperature for 1, 2 and 4 weeks. Subsequently the amounts of nicotine sorbed into the respective polymer materials were extracted from the polymers and analyzed by UV, HPLC and GC. The values for Barex 210 were used as reference levels.

As explained above PTN, marketed through Shell, is chemically very similar to PEN. In polymer chemistry it is a commonly accepted principle that close chemical similarity implies similar physical/chemical properties. Hence the above good results for PEN implies that also PTN has good nicotine barrier properties.

The nicotine impermeable polymers PEN and PTN of the invention can be used alone in film applications or may be combined with other barrier materials in a laminate to further improve the barrier characteristics of the packaging material. Suitable materials for laminating are metal, especially aluminium, foils and other polymers, e.g. polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), and fluoropolymers, all of which are good oxygen and water barriers. Other polymer materials also suitable are

ethylene vinyl alcohol copolymer (EVOH) and polyvinyl alcohol (PVA), which are excellent oxygen barriers, and ionomers (i.e. ionically crosslinked thermoplastic polymers, whereof Surlyn<sup>®</sup> from DuPont is an example), polyethylene (PE), and polypropylene (PP), which have good water barrier properties.

5 LCP is most suitable for use in injection molded applications. PEN, PTN and LCP may be alloyed with other polymers, such as PET. Such an alloy can then be processed as PET, but due to the incorporation of PEN, PTN or an LCP the alloy is conferred superior barrier properties compared to pure PET.

10 The invention will now be further described and illustrated by reference to the following example. It should be noted that this example should not be construed as limiting the invention in any way.

### Example 1

15 An endless sheet of aluminium foil, which optionally on one face is laminated with a thin polymer layer, of e.g. polyethylene or polyethylene terephthalate, is rolled off from a storage roll and passes an applicator which on the other side of the aluminium foil or aluminium foil laminate applies a continuous layer of PEN, PTN or an LCP, by means of an extrusion coating device. The thickness of the aluminum foil is within the range of 5 – 50  $\mu\text{m}$ , preferably within the range of 8 – 20  $\mu\text{m}$ . The amount of applied polymer may vary, but the thickness thereof is preferably such that a well integrated and substantially  
20 intact layer is formed after drying. A suitable thickness range of PEN, PTN or an LCP is 1 – 100  $\mu\text{m}$ , preferably 8 – 50  $\mu\text{m}$ .

Subsequently patch pouches are manufactured by dividing the laminate into two sheets forming an upper and a lower part of the patch pouch. Subsequently and by means of a vacuum device a nicotine-containing patch is placed on one of the sheets whereupon  
25 the other sheet is placed on the patch. Finally the sheets are heat sealed together along their edges to form a pouch.

In Example 1 the nicotine impermeable materials are used to make a package which totally encloses a nicotine-containing product. The present materials are also useful for partially enclosing and/or for sealing a package for a nicotine-containing product.  
30 PEN, PTN and LCP, may also be used for all other applications where presently Barex<sup>®</sup> is used. One such application is the sealing of polymer tubes, containing polymer plugs with nicotine, for the nicotine inhaling device presently marketed by Pharmacia & Up-

john and in essence being disclosed in US 5,501,236. Also said polymer tubes may be made of the materials according to the present invention. Such tubes may e.g. be made by injection molding. The materials may also be used in blisters for nicotine chewing gums or tablets and for sealing glass flasks containing nicotine nasal spray.

- 5           The materials are also suitable for packages wherein dosage forms such as tablets, lozenges or similar are cast directly into the package. Thereby the package is to the extent necessary formed as mould(s) into which is cast the substance to be formed into tablets, lozenges or similar, said material achieving its final shape and form upon solidification in the package. In each such package may e g be cast one or more tablets, lozenges etc.
- 10           After casting the package may be folded or likewise to provide for a nicotine-impermeable package for the cast tablets, lozenges etc. If necessary the package material may be provided with some added material or thin sheet accounting for that the substance which is cast will not stick to the package material.

## CLAIMS

1. A material for packaging a nicotine-containing product, characterized in that it comprises a polymer based on dimethyl-2,6-naphthalene dicarboxynate and/or 2,6-naphthalene dicarboxylic acid monomers.
2. A material for packaging a nicotine-containing product, characterized in that the material comprises a liquid crystal polymer, LCP.
3. A material according to claim 1, characterized in that the polymer is polyethylene naphthalate, PEN.
4. A material according to claim 1, characterized in that the polymer is polytrimethylene naphthalate, PTN.
5. A material according to claim 2, characterized in that the LCP comprises hydroxy benzoic acid and hydroxy naphthenic acid.
6. A material according to any one of the preceding claims, characterized in that it further comprises other polymer(s), preferably one or more of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
7. A material according to anyone of the preceding claims, characterized in that it is laminated with one or more metal and/or polymer foil(s).
8. A material according to claim 7, characterized in that it is laminated with aluminum foil.

9. A material according to anyone of the preceding claims, characterized in that it is used for totally enclosing, partially enclosing and/or for sealing a package for a nicotine containing product.

5 10. A material according to anyone of the preceding claims, characterized in that it is used for a package that is provided with moulds or equivalent into which is cast a substance that upon solidification in the package receives its final form and shape.

10 11. A material according to claim 10, characterized in that it is used for a package in which are directly cast tablets or lozenges.

15 12. A material according to anyone of the preceding claims, characterized in that it is used for packaging a patch for transdermally administering nicotine, a nicotine containing chewing gum, a nicotine containing tablet, a spray for nasal administration of nicotine, or a device for inhaling nicotine.

13. Use of a material according to anyone of the preceding claims for the manufacturing of a package for keeping nicotine-containing products.

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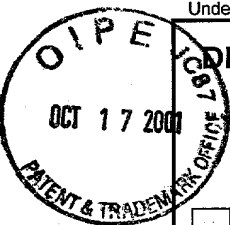


PTO/SB/01 (03-01)

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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	P02232US0
First Named Inventor	Gustav Levander, et al.
<b>COMPLETE IF KNOWN</b>	
Application Number	Not Yet Assigned
Filing Date	July 20, 2001
Group Art Unit	N/A
Examiner Name	Not Yet Assigned

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

MATERIALS FOR PACKAGING NICOTINE-CONTAINING PRODUCTS

(Title of the Invention)

the specification of which

☐ is attached hereto  
OR

☒ was filed on (MM/DD/YYYY) 7-20-2001 as United States Application Number or PCT International

Application No. PCT/SE00/00017 and was amended on (MM/DD/YYYY) (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
PCT/SE00/00017 9900215-6	Sweden	1-12-2000	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Sweden	1-26-1999	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

**Declaration for Utility or Design Patent Application**

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Dated: October 17, 2001

Signature: (Melissa W. Acosta)

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

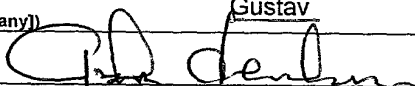
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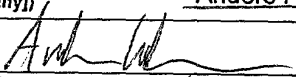
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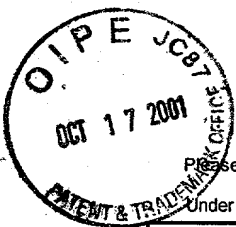
State

ZIP SE-217 54

Country Sweden

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.





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### POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	Not Yet Assigned
Filing Date	7-20-2001
First Named Inventor	Gustav Levander, et al.
Title	"Materials For Packaging Nicotine-Containing Products"
Group Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket No.	HO-P02232US0

I hereby appoint:

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I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.  
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

#### SIGNATURE of Applicant or Assignee of Record

Assignee	Pharmacia AB
Name	JOHN HEDENSTROM
Signature	<i>John Hedenstrom</i>
Date	July 16, 2001

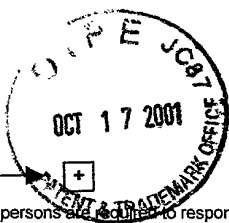
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. See below\*.

☐ \*Total of 1 forms are submitted.

#### POA or Authorization of Agent

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Dated: 10/17/2001 Signature: *Melissa W. Acosta* (Melissa W. Acosta)



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## DECLARATION

## ADDITIONAL INVENTOR(S) Supplemental Sheet

Page 1 of 1

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
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Inventor's Signature		Date	
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Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any])		Family Name or Surname	
Inventor's Signature		Date	
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